



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,510	10/19/2001	Ben-Zion Dolitzky	1662/54902	5381

26646 7590 08/27/2003

KENYON & KENYON  
ONE BROADWAY  
NEW YORK, NY 10004

EXAMINER

BARTS, SAMUEL A

ART UNIT PAPER NUMBER

1621

DATE MAILED: 08/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Applicant No.

10/045,510

Applicant(s)

DOLITZKY ET AL.

Examiner

Samuel A Barts

Art Unit

1621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Priority Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-94 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-94 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-2, drawn to venlafaxine base, classified in class 564, subclass 305.
  - II. Claims 10, 18-31, 56-57 and 59-75, drawn to crystalline forms of venlafaxine, classified in class in class 564, subclass 305.
  - III. Claims 3-9 and 11-17, drawn to a process of making a crystalline form of venlafaxine, classified in class in class 564, subclass 305.
  - IV. Claims 32-34 drawn to a process of making a crystalline form of venlafaxine, classified in class in class 564, subclass 305.
  - V. Claims 35-36 drawn to a process of making a crystalline form of venlafaxine, classified in class in class 564, subclass 305.
  - VI. Claims 37-38 drawn to a process of making a crystalline form of venlafaxine, classified in class in class 564, subclass 305.
  - VII. Claims 39-40 drawn to a process of making a crystalline form of venlafaxine, classified in class in class 564, subclass 305.
  - VIII. Claims 41-44 drawn to a process of making a crystalline form of venlafaxine, classified in class in class 564, subclass 305.
  - IX. Claim 45 drawn to a process of making a crystalline form of venlafaxine, classified in class in class 564, subclass 305.

Art Unit: 1621

- X. Claim 46, drawn to a process of making a crystalline form of venlafaxine, classified in class in class 564, subclass 305.
- XI. Claim 47 drawn to a process of making a crystalline form of venlafaxine, classified in class in class 564, subclass 305.
- XII. Claim 48 to a process of making a crystalline form of venlafaxine, classified in class in class 564, subclass 305.
- XIII. Claim 49 drawn to a process of making a crystalline form of venlafaxine, classified in class in class 564, subclass 305.
- XIV. Claim 50-54 drawn to a process of making a crystalline form of venlafaxine, classified in class in class 564, subclass 305.
- XV. Claim 55 drawn to a process of making a crystalline form of venlafaxine, classified in class in class 564, subclass 305.
- XVI. Claim 58 drawn to a process of making a crystalline form of venlafaxine, classified in class in class 564, subclass 305.
- XVII. Claims 76-80 drawn to a process of making a crystalline form of venlafaxine, classified in class in class 564, subclass 305.
- XVIII. Claims 81-94 drawn to a process of making a crystalline form of venlafaxine, classified in class in class 564, subclass 305.

The inventions are distinct, each from the other because of the following reasons:

Art Unit: 1621

2. Inventions II and {III-XVIII} are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product as claimed can be made by another and materially different process. Applicant is reminded that should the product be elected and found allowable, the claims corresponding to the process of making the same compound will be rejoined.

3. Inventions I and {II-XVIII} are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are not disclosed as capable of use together and they have different modes of operation

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. Claims 10, 18-31, 56-57 and 59-75 are generic to a plurality of disclosed patentably distinct species comprising each different crystalline Form of Venlafaxine. Applicant is required under 35 U.S.C. 121 to elect a single crystalline Form of Venlafaxine, even though this requirement is traversed.

Art Unit: 1621

Should applicant traverse on the ground that the crystalline forms are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the crystalline form to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. A telephone call was made to Siu K. Lo on 8/21/03 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel A Barts whose telephone number is 703-308-4630. The examiner can normally be reached on 6:30-3:00.

Art Unit: 1621

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johan Richter can be reached on 308-1235. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A handwritten signature in black ink, appearing to read 'S A Barts', is positioned above the printed name.

Samuel A Barts  
Primary Examiner  
Art Unit 1621

s.b.